



**Clozapine REMS Program**  
**Prescriber Professional Society**  
**Meeting**

August 18, 2021



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# Demonstration of REMS Website

The screenshot shows the Clozapine REMS website. At the top, there's a navigation bar with the logo "CLOZAPINE REMS" and the tagline "The Single Shared System for Clozapine No Blood, No Drug™". Below the logo, there's a navigation menu with links: Home, Prescriber, Pharmacy, Patient, Resources, and Support. A login section is visible with fields for Username and Password, and a "Sign in" button. Below the login section, there's a yellow banner with the text: "\*\*\*Important Program Update (as of 07/28/2021)\*\*\* Please click to open the IPU". Below the banner, there's a detailed update box with the title "Update: New Clozapine REMS Coming November 15, 2021". The box contains the following text: "Re-Certification and Re-Enrollment Required at [www.newclozapinerems.com](http://www.newclozapinerems.com)." and a list of bullet points: "• ALL Prescribers and Pharmacies **must re-certify** to continue to prescribe or dispense clozapine.", "• ALL Patients continuing on clozapine **must be re-enrolled** by a certified prescriber or prescriber designee.", and "• **Start re-certification and re-enrollment on August 16, 2021 to avoid interruption in patient treatment**". Below the list, there's a link "Go to [www.newclozapinerems.com](http://www.newclozapinerems.com)" and a list of instructions: "• Click on Log-in | Register tab. You need to create new login credentials before re-certifying by clicking on Register.".

Until November 15, 2021, continue to use the ClozapineREMS.com website to manage patients in the REMS.

**1 Prescribers should certify in the new program and enroll their patients as soon as possible and no later than November 15.**

**2 To certify in the modified program, go to NewClozapineREMS.com, as noted on the Important Program Update on the homepage of ClozapineREMS.com.**

## What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L), which can lead to serious and fatal infections. The requirements to prescribe, dispense, and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).



# Demonstration of REMS Website (Continued)

Clozapine REMS

Home Find Pharmacy Patients Prescriber Login | Register

## What is the Clozapine REMS?

The Clozapine REMS (Risk Evaluation and Mitigation Strategy) is a safety program required by the Food and Drug Administration (FDA) to manage the risk of severe neutropenia associated with clozapine treatment.

Severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L), can lead to serious and fatal infections.

### Patient

To receive treatment, a patient must be enrolled in the Clozapine REMS program by a certified doctor.

[Enrollment Information](#)

### Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense clozapine.

If you are the designated authorized representative of a pharmacy, you can certify below.

[Certify Pharmacy](#)

### Prescriber

Healthcare Providers must be certified in the Clozapine REMS to prescribe clozapine for outpatient use.

If you are a clozapine prescriber, you can certify below.

[Certify Prescriber](#)


To facilitate a smooth transition to the modified Clozapine REMS program on November 15, we encourage Prescribers to certify in the modified program now via

- The transition website, [NewClozapineREMS.com](https://www.newclozapinerems.com/), or
- The transition Contact Center at 1-888-586-0758.

***Click Certify Pharmacy on the homepage to start the certification process.***

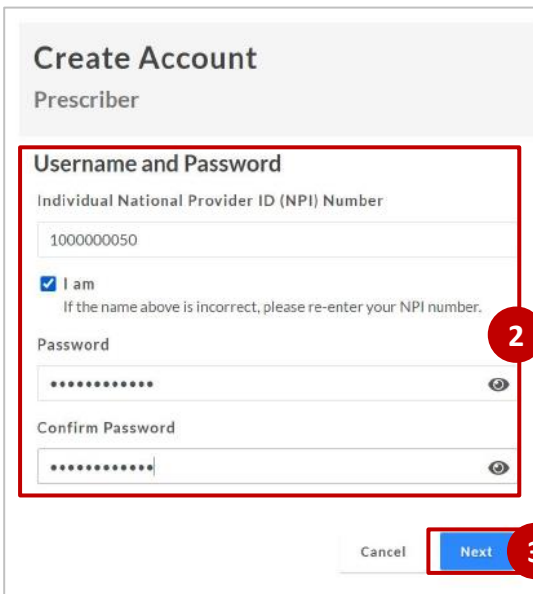
# How to Certify: Register

**All users must create new REMS login credentials. Legacy system credentials will not work in the new system.**



The screenshot shows the Clozapine REMS homepage. At the top, there are navigation links: Wholesaler, Prescribing Information, and Contact Us. Below these, the Clozapine REMS logo is on the left, and a navigation bar contains Home, Find, Pharmacy, Patient, Prescriber, Login, and Register. The Register button is highlighted with a red box and a circled number 1.

**Click Register at the top of the home page to create your account.**

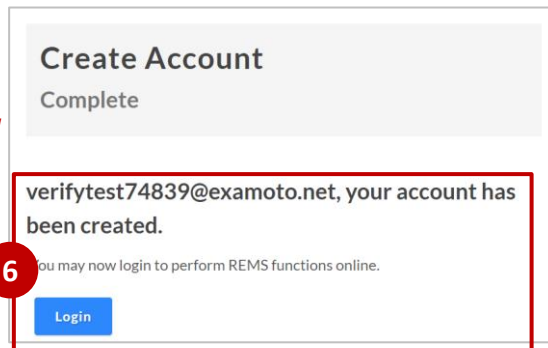


The screenshot shows the 'Create Account Prescriber' form. The 'Username and Password' section is highlighted with a red box and a circled number 2. It includes fields for 'Individual National Provider ID (NPI) Number' (with the value 1000000050), a checkbox for 'I am' (checked), a 'Password' field, and a 'Confirm Password' field. At the bottom, there are 'Cancel' and 'Next' buttons. The 'Next' button is highlighted with a red box and a circled number 3.

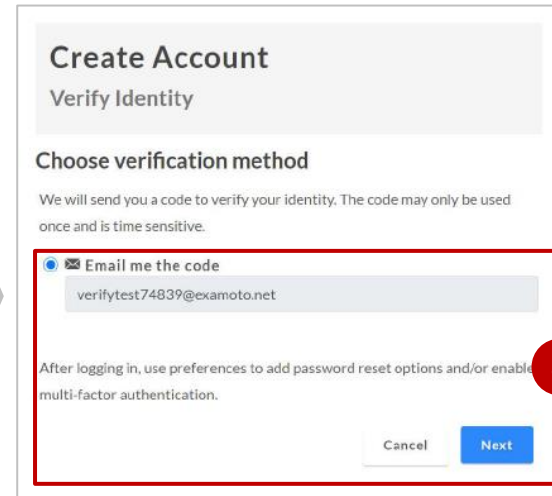
**Type in the Prescriber's Individual NPI Number and password.**

**Then Click Next.**

**On the account confirmation page, click Login to use your new credentials to continue certification.**

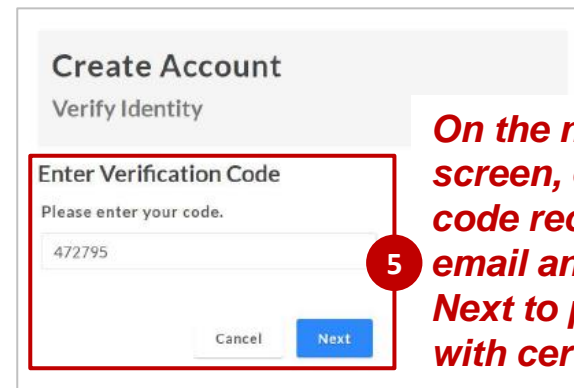


The screenshot shows the 'Create Account Complete' page. It displays the message: 'verifytest74839@examoto.net, your account has been created.' Below this, it says 'You may now login to perform REMS functions online.' and there is a 'Login' button. The 'Login' button is highlighted with a red box and a circled number 6.



The screenshot shows the 'Create Account Verify Identity' page. The 'Choose verification method' section is highlighted with a red box and a circled number 4. It includes the option 'Email me the code' (selected) and a text input field with the value 'verifytest74839@examoto.net'. Below this, there are 'Cancel' and 'Next' buttons.

**You will need to verify your account on the next screen by requesting a code via email and clicking Next.**



The screenshot shows the 'Create Account Verify Identity' page. The 'Enter Verification Code' section is highlighted with a red box and a circled number 5. It includes the text 'Please enter your code.' and a text input field with the value '472795'. Below this, there are 'Cancel' and 'Next' buttons.

**On the next screen, enter the code received via email and click Next to proceed with certification.**

# How to Certify: Knowledge Assessment

Wholesaler Prescribing Information Contact Us

**CLOZAPINE REMS**

Home Find Pharmacy Pa **1 Prescriber** Login Register

**Prescriber**

Prescribers must be certified in the Clozapine REMS to prescribe for outpatient use.

To certify as a prescriber:

- 1 Review the Prescribing Information**  
Review each drug's Prescribing Information:
  - Clozaril®
  - Versacloz®
  - Clozapine Tablets, USP (Accord Healthcare)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Mayne Pharma)
  - Clozapine Tablets, USP (Mayne Pharma)
  - Clozapine Tablets, USP (Mylan Pharmaceuticals)
  - Clozapine ODT (Mylan Pharmaceuticals)
  - Clozapine Tablets, USP (Mylan Pharmaceuticals)
  - Clozapine Tablets, USP (Sun Pharmaceutical Industries)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
- 2 Review the Guide for Healthcare Providers**  
Review the [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#).
- 3 Complete the Knowledge Assessment for Prescribers**  
Successfully complete the Knowledge Assessment for Prescribers and submit it to the Clozapine REMS.  
 or
- 4 Complete the Prescriber Enrollment Form**  
Enroll in the Clozapine REMS by completing the Prescriber Enrollment Form and submitting it to the Clozapine REMS.  
 or


**Prescriber Materials**

- Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
- Knowledge Assessment for Prescribers
- Prescriber Enrollment Form
- Patient Enrollment Form
- Patient Status Form
- ANC Lab Reporting Form
- Prescriber Designee Enrollment Form
- What's Changed in the Clozapine REMS for Prescribers?


**1** Click Prescriber at the top of the home screen to access the certification screen.

**2** Following completion of Steps 1 and 2, complete the Knowledge Assessment by clicking Online under Step 3.

# How to Certify: Knowledge Assessment (Continued)



Home Prescriber Test Prescriber000822

 **Prescriber - Knowledge Assessment**

Knowledge Assessment for Prescribers

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

0 of 12 questions in progress

1 . All clozapine products are only available under the single shared Clozapine REMS.

☐ True

☐ False

2 . Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

☐ True

☐ False

3 . Severe neutropenia is defined as:

☐ A. A white blood cell count (WBC) less than 2000/ $\mu$ L

☐ B. An absolute neutrophil count (ANC) less than 1000/ $\mu$ L


***Prescribers must successfully complete a 12-question Knowledge Assessment.***


***Three attempts are allowed. If you exceed this number, then call the Contact Center.***

***Following successful completion of the Knowledge Assessment, Prescribers can continue the certification process.***

# How to Certify: Enrollment


[Wholesaler](#) [Prescribing Information](#) [Contact Us](#)









 [Home](#) [Find](#) [Pharmacy](#) [Patient](#) [Prescriber](#) [Login](#) | [Register](#)

 **Prescriber**  
Prescribers must be certified in the Clozapine REMS to prescribe for outpatient use.

### To certify as a prescriber:

- 1 Review the Prescribing Information**  
Review each drug's Prescribing Information:
  - Clozaril®
  - Versacloz®
  - Clozapine Tablets, USP (Accord Healthcare)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Aurobindo Pharma USA)
  - Clozapine Tablets, USP (Mayne Pharma)
  - Clozapine Tablets, USP (Mayne Pharma)
  - Clozapine Tablets, USP (Mylan Pharmaceuticals)
  - Clozapine ODT (Mylan Pharmaceuticals)
  - Clozapine Tablets, USP (Mylan Pharmaceuticals)
  - Clozapine Tablets, USP (Sun Pharmaceutical Industries)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
  - Clozapine Tablets, USP (Teva Pharmaceuticals USA)
- 2 Review the Guide for Healthcare Providers**  
Review the [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#).
- 3 Complete the Knowledge Assessment for Prescribers**  
Successfully complete the Knowledge Assessment for Prescribers and submit it to the Clozapine REMS.  
[Online](#) or [Print](#)
- 4 Complete the Prescriber Enrollment Form**  
Enroll in the Clozapine REMS by completing the Prescriber Enrollment Form and submitting it to the Clozapine REMS.  
[Online](#) or [Print](#)

  
**Prescriber Materials**

<a href="#">Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</a>	
<a href="#">Knowledge Assessment for Prescribers</a>	
<a href="#">Prescriber Enrollment Form</a>	
<a href="#">Patient Enrollment Form</a>	
<a href="#">Patient Status Form</a>	
<a href="#">ANC Lab Reporting Form</a>	
<a href="#">Prescriber Designee Enrollment Form</a>	
<a href="#">What's Changed in the Clozapine REMS for Prescribers?</a>	

**After completing Step 3, Prescribers need to complete enrollment by clicking Online under Step 4.**



# How to Certify: Enrollment (Continued)



Home Find ▾ Prescriber ▾ KENDRICK ADNAN ▾

## Prescriber Enrollment

KENDRICK ADNAN

Prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) are not required to be certified in the Clozapine REMS. Patients in this setting are required to be enrolled in the Clozapine REMS in order to receive clozapine.

### Instructions

Clozapine is only available through the Clozapine REMS (Risk Evaluation and Mitigation Strategy). In order to become certified and prescribe clozapine, you must:

1. Review the Prescribing Information for clozapine and *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete and submit the *Knowledge Assessment for Prescribers*
3. Complete and submit this one-time Clozapine REMS Prescriber Enrollment Form

Prescriber Information

Individual NPI Number

(Select address type to populate form)

Use individual NPI to populate form: 1811090103

☒ Office Address ☐ Mailing Address

First Name

M.I.

Last Name

KENDRICK

M

ADNAN

Individual DEA Number\*

Email Address\*

Individual DEA Number

kad@examoto.net

Credentials\*

Clinic/Practice Name\*

☐ MD ☐ NP ☐ PA ☐ DO ☐ Other

Clinic/Practice Name

Address Line 1\*

Address Line 2

555 SOUTH PARK

Address Line 2

City\*

State\*

ZIP Code\*

BRECKENRIDGE

Colorado

80424

Phone\*

Ext.

Fax

970-453-1010

nnn...

970-453-5407

Preferred Method of Contact

Preferred Time of Contact

☐ Text ☐ Email ☐ Call

☐ Morning ☐ Afternoon ☐ Evening

**The Prescriber starts the Prescriber Enrollment form online by filling in information about themselves (e.g., NPI, practice name, credentials, contact information).**

**Prescribers should also enter their contact preferences.**

# How to Certify: Enrollment (Continued)

## Prescriber Responsibilities

I have:

- Reviewed the drug's Prescribing Information for clozapine.
- Reviewed the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers.
- Successfully completed the Knowledge Assessment for Prescribers and submitted it to the Clozapine REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient or caregiver on the risks associated with clozapine, including severe neutropenia, and the Clozapine REMS requirements including to report signs of infection using A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia.
- Provide a copy of the Guide to the patient unless clinical judgment indicates that the patient's adherence to the treatment regimen will be negatively impacted by providing the Guide.
- Assess the patient's absolute neutrophil count (ANC). Document and submit the ANC to the Clozapine REMS using the Patient Enrollment Form.
- Enroll the patient in the Clozapine REMS by completing and submitting the Patient Enrollment Form to the Clozapine REMS.

During treatment; according to the monitoring frequency in the Prescribing Information, I must

- Assess the patient's ANC and monitoring frequency.
- For patients with an ANC that falls below the acceptable range: Assess the patient's health status for appropriateness of continuing treatment.

During treatment, monthly, I must:

- Document and submit the ANC results, the monitoring frequency, and appropriateness for continuing treatment to the Clozapine REMS using the Patient Status Form.

After treatment discontinuation; according to the monitoring frequency in the Prescribing Information, I must:

- Assess the patient's ANC. Document and submit the ANC results to the REMS program using the Patient Status Form.

I understand that if I do not maintain compliance with the requirements of the Clozapine REMS, I will no longer be able to prescribe Clozapine.

I understand that personnel from the Clozapine REMS or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS.

I understand that clozapine manufacturers or their agents and contractors may contact me via phone, mail or email to survey me on the effectiveness of the program requirements for the Clozapine REMS.

3

***Next the Prescriber must review their responsibilities in the REMS.***

Sign Type Signature

Please use your mouse or stylus to sign below

Clear

4

***The last step is to sign the enrollment form and submit it by clicking Sign and Submit.***

I authorize the above signature to be the legally binding equivalent of my handwritten signature.

Sign and Submit

# How to Certify: Certification Completion

The screenshot displays the 'Prescriber' dashboard for user 1310000001. On the left sidebar, there are four main menu items: 'Prescriber Certification', 'Edit Personnel', 'Enroll Patients in', and 'Manage Patients'. The 'Prescriber Certification' item is highlighted with a red box. A red line connects this box to a larger, magnified view of the 'Prescriber Certification' card in the center of the dashboard. This card shows a green checkmark icon and the text 'You are currently certified in the Clozapine REMS.' The right side of the dashboard contains two sections: 'Prescriber Materials' with a download icon and a list of documents including 'Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers', and 'Upload Form' with an upload icon and a 'Browse' button. The text 'Uploads must be in PDF format.' is also visible.

***Successful completion of Enrollment and the Knowledge Assessment result in a Prescriber being marked as certified on the Prescriber Dashboard.***

# How to Certify: Adding Prescriber Designees

The screenshot shows the 'Prescriber' dashboard for user 1310000001. The left sidebar contains four main sections: 'Prescriber Certification' (with a green checkmark), 'Edit Personnel' (highlighted with a red box), 'Enroll Patients in the Clozapine REMS', and 'Manage Patients'. The 'Edit Personnel' section has a sub-header 'Edit, Add, or Remove Designees from the Clozapine REMS' and a '→ Manage' button. A red callout line extends from this button to a larger, detailed view of the 'Edit Personnel' section. This detailed view shows the same sub-header and a '→ Manage' button. Below the detailed view is an 'Upload Form' section with a note 'Uploads must be in PDF format.' and a 'Browse' button.

***Certified Prescribers can designate individuals, known as Prescriber Designees, to conduct certain activities in the REMS on their behalf.***

***Under Edit Personnel on the Prescriber Dashboard, click Manage to add Prescriber Designee(s).***

***Follow instructions on the screens that follow to invite a designee to act on your behalf either via the REMS website and the Contact Center or by via the Contact Center only.***

# How to Enroll Patients

**Prescriber**  
1310000001

**Prescriber Certification**  
You are currently certified in the Clozapine REMS.

**Edit Personnel**  
Edit, Add, or Remove Designees from the Clozapine REMS  
→ Manage

**Enroll Patients in the Clozapine REMS**  
You must enroll your patients in the Clozapine REMS.  
→ Enroll Patient

**Manage Patients**  
Manage your Clozapine REMS patients.  
→ Manage Patients

**Prescriber Materials**

- Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
- Knowledge Assessment for Prescribers
- Prescriber Enrollment Form
- Patient Enrollment Form
- Patient Status Form
- ANC Lab Reporting Form
- Prescriber Designee Enrollment Form
- What's Changed in the Clozapine

**Enroll Patients in the Clozapine REMS**  
You must enroll your patients in the Clozapine REMS.  
→ Enroll Patient

**Browse** Or drop files here

***Under Enroll Patients in the Clozapine REMS on the Prescriber Dashboard, click Enroll Patient to add patients managed by the Prescriber.***

# How to Enroll Patients (Continued)

## Patient Enrollment

Patient Enrollment

First Name

Last Name

First Name

Last Name

Gender

Date of Birth

☐ Male ☐ Female ☐ Other

mm/dd/yyyy

Race

☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Caucasian ☐ Native Hawaiian or Other Pacific Islander ☐ Other

Ethnicity

☐ Hispanic or Latino ☐ Not Hispanic or Latino

Phone

Email

Phone

Email

☐ Does the patient have a permanent address?

Zip Code

***The Prescriber completes the Patient Enrollment form online by filling in information about the patient (e.g., name, DOB, demographics),...***

***...contact information (e.g., phone, email),...***

## How to Enroll Patients (Continued)

**Patient Information**

Is this patient actively on clozapine therapy?

☐ Yes ☐ No ☐ Unknown

If Yes, what is this patient's current monitoring frequency?

**Monitoring**

Frequency

Daily Weekly Monthly

**Baseline Lab Information**

Blood Draw Date ANC (per  $\mu$ L)

MM/DD/YYYY 0

**Benign Ethnic Neutropenia (BEN) Patient Attestation**

☒ Benign Ethnic Neutropenia (BEN)

Complete this section to indicate that this is a patient with documented benign ethnic neutropenia.

☐ A BEN patient designation provides a separate ANC monitoring algorithm for the patient. The BEN designation is a permanent status.

**Hospice Care Patient Attestation**

☒ Hospice Care

For hospice patients (i.e., terminally-ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every 6 months after a discussion with the patient and his/her caregiver.

☐ This is a hospice care patient.

Cancel **Enroll Patient**

3 ...information about clozapine therapy (e.g., therapy status, monitoring frequency),...

4 ...baseline lab information (e.g., draw date, ANC),...

5 ...BEN status (if applicable),...

6 ...and hospice status (if applicable).

7 Then click Enroll Patient.

# How to Use the Patient Status Form

**Prescriber**  
1310000001

**Prescriber Certification**  
You are currently certified in the Clozapine REMS.

**Edit Personnel**  
Edit, Add, or Remove Designees from the Clozapine REMS  
→ Manage

**Enroll Patients in the Clozapine REMS**  
You must enroll your patients in the Clozapine REMS.  
→ Enroll Patient

**Manage Patients**  
Manage your Clozapine REMS patients.  
→ Manage Patients

**Prescriber Materials**

- Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
- Knowledge Assessment for Prescribers
- Prescriber Enrollment Form
- Patient Enrollment Form
- Patient Status Form
- ANC Lab Reporting Form
- Prescriber Designee Enrollment Form
- What's Changed in the Clozapine REMS for Prescribers?

***To complete and submit a Patient Status Form, click the Manage Patients button on the Prescriber Dashboard.***

**Manage Patients**  
Manage your Clozapine REMS patients.  
→ Manage Patients



# How to Use the Patient Status Form (Continued)

## Manage Patients



### Manage Patients

Manage your Clozapine REMS patients.

Enroll Patient

Show 10 entries

Search My Patient List:

Edit	Name Date of Birth	REMS Patient ID	Population	Monitoring	Treatment Status	Patient Status Form (PSF)
	PatientPat Smith 06/27/1954	CPDemoPatDiscont	General	N/A	Discontinued	Add PSF
	PatientPat Smith 06/27/1954	CMDemo3xLate	General	3 times a week Add ANC	Active	15 days Late Add PSF
	PatientPat Smith 06/27/1954	CMDemoWeekly	General	Weekly Add ANC	Active	Add PSF
	PatientPat Smith 06/27/1954	CMDemoInt01	General	3 times a week Add ANC	Interrupted	Add PSF
	PatientTerry Smitt 09/22/1989	CMDemoEvy2Wk	General	Every 2 weeks Add ANC	Active	Add PSF
	PatientPat Smith 06/27/1954	CMDemoMonthly	General	Monthly Add ANC	Active	Due in 3 days Add PSF
	PatientPat Smith 07/15/1965	CPPatEg30CI37	General	Weekly Add ANC	Active	6 days Late Add PSF
	PatientPat Smith 07/15/1965	CMDemoBenMonthly	BEN	Monthly Add ANC	Active	Add PSF
	PatientJulie Williams 06/13/1970	PA1234567	General	Weekly Add ANC	Unkown	Add PSF
	PatientJenn Miller 10/31/1985	PA7654321	General	Weekly Add ANC	Unkown	Add PSF

Edit patient demographics

Showing 1 to 10 of 21 entries

Previous 1 2 3 Next

Return


*On your Manage Patients screen, you can sort by any column (e.g., name, REMS patient ID number) to help you identify the patient you need.*

*To add a Patient Status Form, click the Add PSF button on the appropriate patient's row.*

# How to Use the Patient Status Form (Continued)

Beginning November 15, 2021, Prescribers must complete and submit the Patient Status Form to the REMS for each enrolled patient who is continuing treatment with clozapine.


## Patient Status Form (PSF)

 **Patient Status Form (PSF)**  
Assess the patient by obtaining complete blood counts, including the absolute neutrophil count (ANC) as described in the Prescribing Information. This form must be completed monthly for each patient continuing treatment with clozapine.

 **Patient (Population: General)** Enrolled as of 2/26/2021 


Name:	PatientTerry Smitt	Zip Code:	28601
Date of Birth:	9/22/1989	Phone:	920-723-6334
REMS Patient ID:	CMDemoEvy2Wk	Email:	CMPatient3t@examoto.net

1 **Confirm the patient information,...**

 **Patient Status**


Are you monitoring the patient as recommended in the Prescribing Information?

☐ Yes ☒ No

 **Monitoring**

Current Patient Monitoring Frequency: Every 2 weeks  
Change the patient's monitoring frequency to:

Frequency  ☒ Weekly ☐ Monthly

 **Hospice Care**

For hospice patients (i.e., terminally-ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every 6 months after a discussion with the patient and his/her caregiver.

I want to change this patient's monitoring frequency to once every 6 months for a hospice patient.

☐ This is a hospice patient

2 **...indicate the patient's status (e.g., monitoring frequency, hospice),...**

Did the patient experience any adverse event(s) due to clozapine-induced neutropenia (e.g. infection)?

☐ Yes ☒ No

3 **...mark whether the patient had an adverse event and update their status, if necessary,...**


☒ **Benign Ethnic Neutropenia (BEN)**

Complete this section to indicate that this is a patient with documented benign ethnic neutropenia.


☐ A BEN patient designation provides a separate ANC monitoring algorithm for the patient. The BEN designation is a permanent status.

4 **...and note that the patient has benign ethnic neutropenia (BEN), if appropriate.**


## How to Use the Patient Status Form (Continued)

 Reporting ANC Lab Data

[Add Supplemental ANC](#)

Blood Draw Date	General Patient Population	ANC (per $\mu\text{L}$ )
<input type="text" value="MM/DD/YYYY"/>	<input type="radio"/> Normal Range ( $\geq 1500/\mu\text{L}$ )	<input type="text"/> 
Reason for Missing Lab	<input type="radio"/> Mild Neutropenia (1000 to 1499/ $\mu\text{L}$ )	
<input type="radio"/> Patient Refused	<input type="radio"/> Moderate Neutropenia (500 to 999/ $\mu\text{L}$ )	
<input type="radio"/> Clinician Discretion	<input type="radio"/> Severe Neutropenia ( $< 500/\mu\text{L}$ )	
<input type="radio"/> Extrinsic factors (e.g., weather, transportation issues)		

Blood Draw Date	General Patient Population	ANC (per $\mu\text{L}$ )
<input type="text" value="MM/DD/YYYY"/>	<input type="radio"/> Normal Range ( $\geq 1500/\mu\text{L}$ )	<input type="text"/> 
Reason for Missing Lab	<input type="radio"/> Mild Neutropenia (1000 to 1499/ $\mu\text{L}$ )	
<input type="radio"/> Patient Refused	<input type="radio"/> Moderate Neutropenia (500 to 999/ $\mu\text{L}$ )	
<input type="radio"/> Clinician Discretion	<input type="radio"/> Severe Neutropenia ( $< 500/\mu\text{L}$ )	
<input type="radio"/> Extrinsic factors (e.g., weather, transportation issues)		

[Cancel](#) [Save](#)

**Report ANC lab data or reason for missing lab.**

**Note that the system will provide the number of entry lines necessary based on the patient's monitoring frequency.**

**After entering all required information, click Save to submit the Patient Status Form to the REMS.**

## Patient Status Form (PSF)

### Patient Treatment Status

Due to the last ANC Value entered indicating either the patient has moderate neutropenia (ANC 500-999/ $\mu$ L for the BEN population) or severe neutropenia (ANC <500/ $\mu$ L for general population this patient's treatment status has been set to interrupted. You may choose to discontinue treatment or provide a treatment rationale below:

- ☒ Interrupt Treatment
- ☐ Treatment Rationale
  - Benefits of continuing c
- ☐ Discontinue Treatment

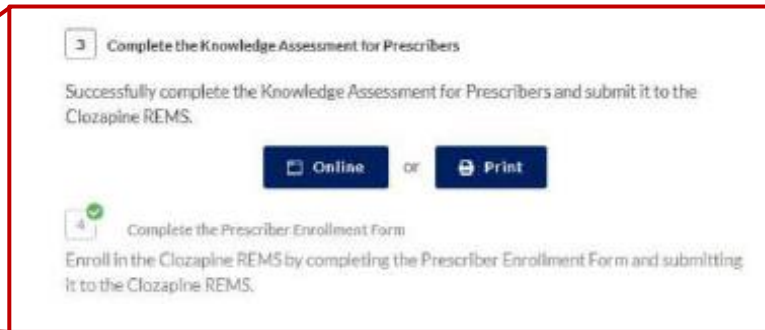
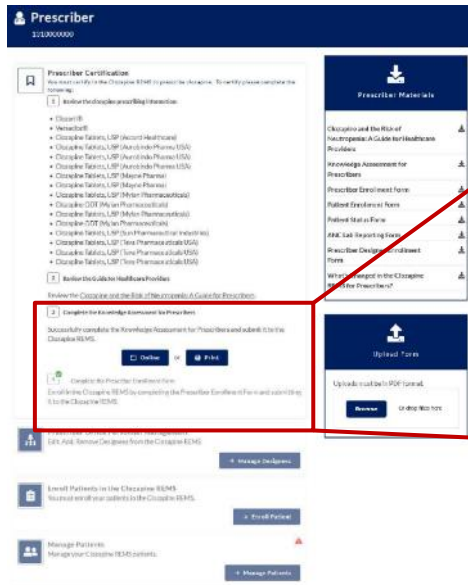
Benefits of continuing clozapine treatment outweigh the risk of neutropenia. Until: (not to exceed 6 months)

**Save**

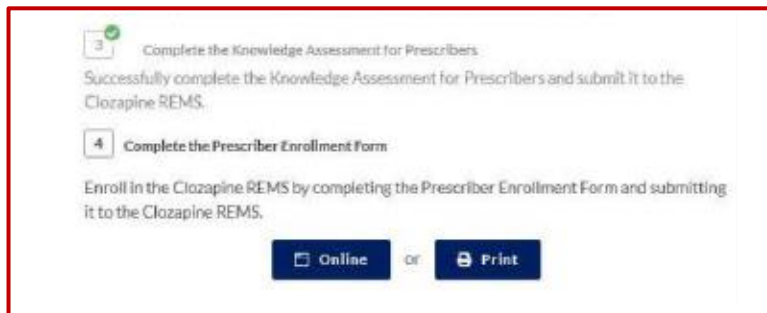
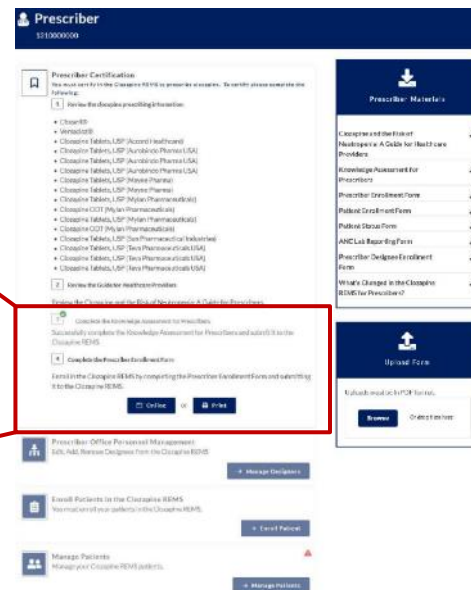
***In this scenario, the Prescriber should select one of the following: Interrupt Treatment, Treatment Rationale, or Discontinue Treatment before saving the Patient Status Form.***

# How to Troubleshoot Common Issues: Incomplete Certification

Prescribers must successfully complete the Knowledge Assessment AND enrollment to be certified; if a user stops in the middle of certification, then one of these elements may be incomplete. In this case, the Prescriber dashboard will only show a check mark next to one of the two activities.



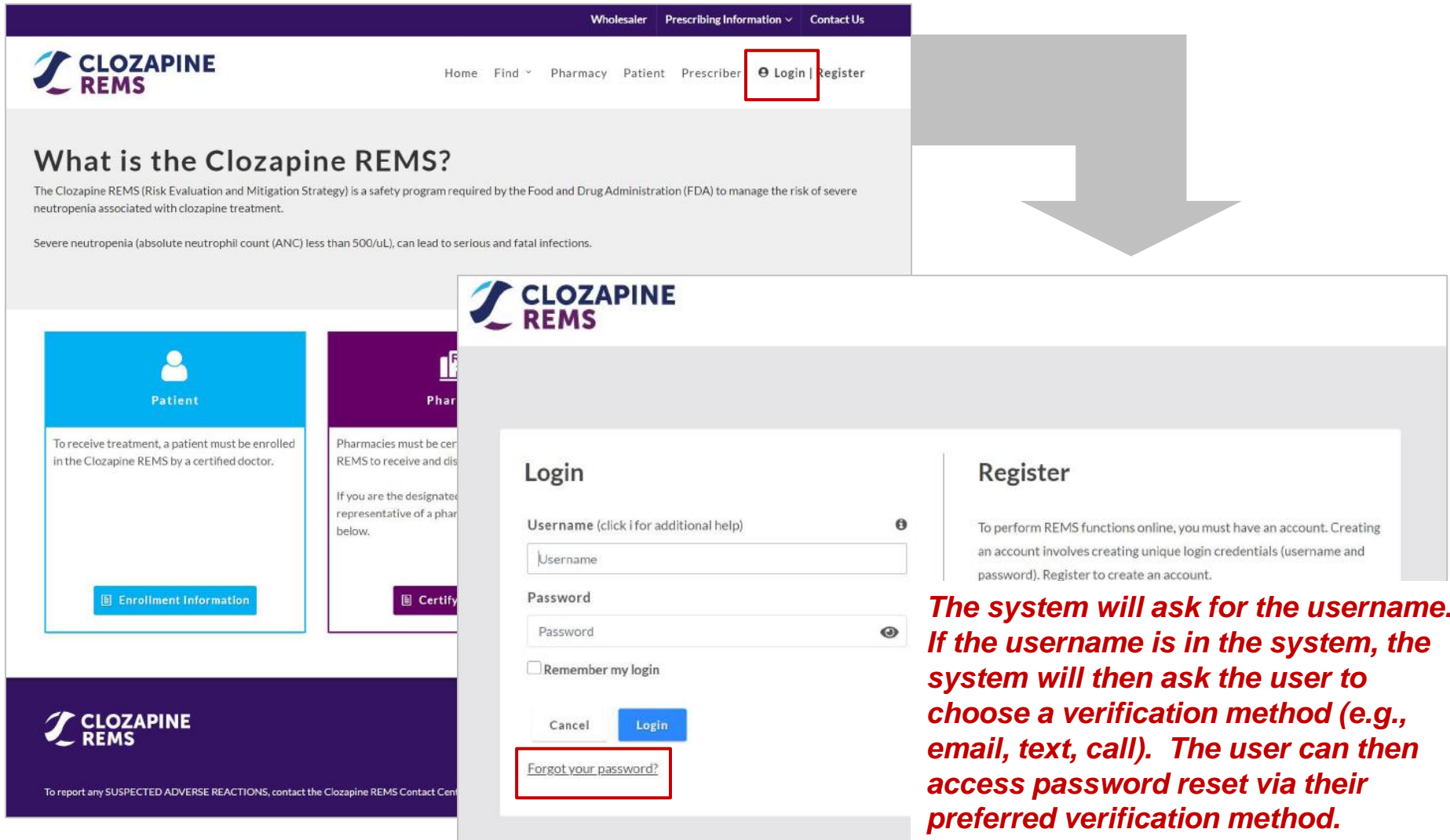
**Incomplete Knowledge Assessment with Complete Enrollment**



**Incomplete Enrollment with Complete Knowledge Assessment**

# How to Troubleshoot Common Issues: Lost/Forgotten Password

Prescribers and Prescriber Designees can reset their own password from the Login screen.



The screenshot displays the Clozapine REMS website interface. At the top, a navigation bar includes links for 'Wholesaler', 'Prescribing Information', and 'Contact Us'. Below this, a secondary navigation bar features 'Home', 'Find', 'Pharmacy', 'Patient', 'Prescriber', and a highlighted 'Login | Register' link. The main content area is titled 'What is the Clozapine REMS?' and provides information about the program's purpose and risks. A large grey arrow points from the 'Login | Register' link to the 'Login' section of the page. The 'Login' section contains fields for 'Username' and 'Password', a 'Remember my login' checkbox, and 'Cancel' and 'Login' buttons. A red box highlights the 'Forgot your password?' link located below the 'Login' button. The 'Register' section is also visible, explaining the requirements for creating an account.

**Login**

Username (click i for additional help)

Username

Password

☐ Remember my login

Cancel Login

[Forgot your password?](#)

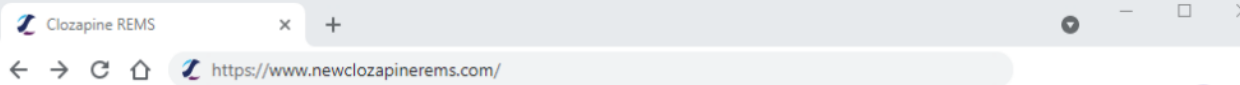
**Register**

To perform REMS functions online, you must have an account. Creating an account involves creating unique login credentials (username and password). Register to create an account.

*The system will ask for the username. If the username is in the system, the system will then ask the user to choose a verification method (e.g., email, text, call). The user can then access password reset via their preferred verification method.*



# Closing



Home Find Pharmacy Patients Prescriber Login | Register

## What is the Clozapine REMS?


The Clozapine REMS (Risk Evaluation and Mitigation Strategy) is a safety program required by the Food and Drug Administration (FDA) to manage the risk of severe neutropenia associated with clozapine treatment.

Severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L), can lead to serious and fatal infections.



### Patient

To receive treatment, a patient must be enrolled in the Clozapine REMS program by a certified doctor.


 [Enrollment Information](#)



### Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense clozapine.

If you are the designated authorized representative of a pharmacy, you can certify below.


 [Certify Pharmacy](#)



### Prescriber

Healthcare Providers must be certified in the Clozapine REMS to prescribe clozapine for outpatient use.

If you are a clozapine prescriber, you can certify below.

 [Certify Prescriber](#)

**Prescribers must certify in the modified program and enroll their patients prior to November 15.**

- **The transition website, [NewClozapineREMS.com](https://www.newclozapinerems.com/), or**
- **The transition Contact Center at 1-888-586-0758.**